



Microdosing in Drug Development: Current Status and Future Perspectives



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*June 16 • 2008 • Maritim Kurhaushotel • Bad Homburg • Germany
One day prior to EUFEPS and Network Conference on June 17-18, 2008*

Workshop organised by

EUFEPS – the European Federation for Pharmaceutical Sciences – for

EUMAPP – the European Union Microdose AMS Partnership Programme



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Scope & Aim & Format

Microdosing is gaining access into drug development, and there is substantial evidence that this methodology is predictive, in many cases. However, can we say that the microdosing-approach is fully verified, and that its place in drug development is well defined? In the Workshop, outcomes of the EUMAPP Project will be presented and put into a wider context, placing microdose predictions beside those of the classical approach. Needs to further verify and validate it will also be discussed, against results obtained by direct comparison between microdosing versus dosing in the pharmacological range.

Additional aims include providing and discussing up-to-the-minute status of microdosing, in podium presentations and discussion sessions. For example, these and other issues will be addressed and discussed in the Workshop: Are there drug class specific concerns? Do biologics behave differently from NCEs? What are the analytical demands, including as to sensitivity and instrumentation, for performing microdosing? Would modelling and simulation enforce the measurements? How well is microdosing accepted by industry and regulators? Are there ethical concerns? Are there technical developments on the analytical side to allow a more widespread use of microdosing? In what direction do future opportunities and developments go?

Scientific Planning Committee

Ole J. Bjerrum (Workshop Chair), University of Copenhagen, Copenhagen DK

Daan J.A. Crommelin, Top Institute Pharma, Leiden NL

Rokus de Zeeuw, BEBO, Assen NL

Colin Garner, Xceleron, York UK

Roeline Jochemsen (Workshop Co-chair), IRIS, Courbevoie FR

Graham Lappin (Workshop Co-chair), Xceleron, York UK

Hans H. Lindén, EUFEPS, Stockholm SE, and

Berend Oosterhuis, PRA International, Zuidlaren NL

Preliminary Programme

Workshop Chair

Ole J. Bjerrum, University of Copenhagen, Copenhagen DK

Workshop Co-Chairs

Roeline Jochemsen, IRIS, Courbevoie FR

Graham Lappin, Xceleron, York UK

9:00	Opening and Welcome and Introduction <i>EUFEPS President, EUMAPP Project Leader and Workshop Chairs</i>
9:15	Classical prediction – based on <i>in vitro</i> and preclinical data <i>Simon Thomas</i> , Cyprotex, Macclesfield UK
9:45	New microdose data produced by the Eumapp Project <i>Roeline Jochemsen</i> , IRIS, Courbevoie FR

10:15	Integrating data form microdosing studies to better predict <i>Simon Thomas</i> , Cyprotex, Macclesfield UK
10:40	Coffee Break
11:00	Combining and comparing with data in the scientific literature: Pharmacology and clinical pharmacology <i>Brian Houston</i> , University of Manchester, Manchester UK
11:40	Classical or contemporary predictive approaches: Any difference? <i>Roeline Jochemsen</i> , IRIS, Courbevoie FR
12:00	Discussion
12:10	Lunch
13:20	Analytical demands and tools to perform microdosing studies AMS first and second generation and LC-MS <i>Graham Lappin</i> , Xceleron, York UK Microdose experiences from an academic lab <i>Kristina Stenström</i> , Lund University, Lund SE
14:10	Regulatory and ethical requirements and issues <i>Rokus de Zeeuw</i> , BEBO, Assen NL
14:30	Contributions to and role of microdosing and the Eumapp Project in the wider perspective: Lessons learnt <i>Malcolm Rowland</i> , University of Manchester, Manchester UK
15:00	Round Table Discussion: Where to go to better predict earlier? Industrialists, academics, regulators and others Moderators: <i>Conference Co-chairs</i> Rapporteurs: <i>Ole J. Bjerrum</i> , University of Copenhagen, Copenhagen DK <i>Rokus de Zeeuw</i> , BEBO, Assen NL <i>Graham Lappin</i> , Xceleron, York UK
16:00	Closing of the Workshop

Proceedings

Plans include that the outcome of the Workshop should be presented in a report article in European journal of Pharmaceutical Sciences and/or other.

Language

English will be the language of the Workshop. No simultaneous translation will be provided.

Registration and Hotel Reservation

Please visit the Conference Website at www.eufeps.org to register for the Workshop and for hotel reservation. There is no registration fee for attending the Workshop.

Workshop Venue

The Workshop will take place at the Maritim Kurhaushotel which is situated right in the heart of the city of Bad Homburg. It is the same venue as for the EUFEPS and Network Conference taking place on June 17-18, 2008. Bad Homburg can be reached by car or light rail (S-Bahn) from the Frankfurt Main Station (Hauptbahnhof) in 15-30 minutes, depending on traffic and train connections. Information on how to get there can be found at the Workshop Website at: www.eufeps.org or www.eumapp.com

Disclaimer/Liability

The Organising Committee and Congrex Sweden AB accept no liability for any injuries/losses incurred by participants, nor loss of, or damage to, any luggage and/or personal belongings.

Useful addresses

**Conference Registration &
Hotel Reservation Secretariat**
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Conference Venue
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Website for Update

For full and update programme, see circulating announcements and consult these websites for update: EUMAPP www.eumapp.com or EUFEPS www.eufeps.org

EUMAPP

is the European Union Microdose AMS Partnership Programme, coordinated by Xceleron Ltd., York UK, and funded by the European Commission. It comprises 10 organisations from 5 different countries (United Kingdom, Sweden, The Netherlands, France and Poland). The aim is to evaluate microdosing for drug development and to arrive at recommendations about how and when it could and should be used.

EUFEPS

is the European Federation for Pharmaceutical Sciences, the mission of which is to advance excellence in the pharmaceutical sciences and innovative drug research and to represent the interests of scientists engaged in drug research and development, drug regulation and drug policymaking. Currently, it links scientific societies and associations in 24 European Countries, and 10+ member institutions. There are around 600 individual members, and EUFEPS Networks are growing in numbers.

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